DEVICE, SYSTEM, AND METHOD FOR CONTRACTING TISSUE IN A MAMMALIAN BODY

PRIORITY CLAIM

[001] This application claims the benefit of U.S. Provisional Application No. 60/480,473, Titled "Method and System for Reducing Mitral Valve Regurgitation" by Eliot Bloom, et al., filed June 20, 2003, which is hereby incorporated by reference.

TECHNICAL FIELD

[002] This invention relates generally to medical devices and particularly to a device, system, and method for contracting tissue in a mammalian body.

BACKGROUND OF THE INVENTION

[003] The heart is a four-chambered pump that moves blood efficiently through the vascular system. Blood enters the heart through the vena cava and flows into the right atrium. From the right atrium, blood flows through the tricuspid valve and into the right ventricle, which then contracts and forces blood through the pulmonic valve and into the lungs. Oxygenated blood returns from the lungs and enters the heart through the left atrium and passes through the bicuspid mitral valve into the left ventricle. The left ventricle contracts and pumps blood through the aortic valve into the aorta and to the vascular system.

[004] The mitral valve consists of two leaflets (anterior and posterior) attached to a fibrous ring or annulus. In a healthy heart, the mitral valve leaflets overlap during contraction of the left ventricle and prevent blood from flowing back into the left atrium. However, due to various cardiac diseases, the mitral valve annulus may become distended, causing the leaflets to remain partially open during ventricular contraction and thus allowing regurgitation of blood into the left atrium. This results in reduced ejection volume from the left ventricle, causing the left ventricle to compensate with a

larger stroke volume. The increased workload eventually results in dilation and hypertrophy of the left ventricle, further enlarging and distorting the shape of the mitral valve. If left untreated, the condition may result in cardiac insufficiency, ventricular failure, and death.

[005] It is common medical practice to treat mitral valve regurgitation by valve replacement or repair. Valve replacement involves an open-heart surgical procedure in which the patient's mitral valve is removed and replaced with an artificial valve. This is a complex, invasive surgical procedure with the potential for many complications and a long recovery period.

[006] Mitral valve repair includes a variety of procedures to reshape or reposition the leaflets to improve closure of the valve during ventricular contraction. Correction of the regurgitation may not require repair of the valve leaflets themselves, but simply a reduction in the size of the mitral valve annulus, which can become distended. A common repair procedure involves implanting an annuloplasty ring on the mitral valve annulus. The annuloplasty ring generally has a smaller diameter than the distended annulus, and when sutured to the annulus, the annuloplasty ring draws the annulus into a smaller configuration, bringing the mitral valve leaflets closer together and providing improved closure during ventricular contraction.

[007] Annuloplasty rings may be rigid, flexible, or have both rigid and flexible segments. Rigid annuloplasty rings have the disadvantage of causing the mitral valve annulus to be rigid and unable to flex in response to the contractions of the ventricle, thus inhibiting the normal movement of the mitral valve that is required for it to function optimally. Flexible annuloplasty rings are frequently made of Dacron® fabric and must be sewn to the annular ring with a line of sutures. Scar tissue formation from the multiple stitches may lead to loss of flexibility and function of the mitral valve. Similarly, combination rings must generally be sutured in place and also cause scar tissue formation and loss of mitral valve flexibility and function.

[008] Annuloplasty rings have been developed that do not require suturing. U.S. Patent No. 6,565,603 discloses a combination rigid and flexible annuloplasty ring that is inserted into the fat pad of the atrioventricular groove,

which surrounds the mitral valve annulus. Although this device avoids the need for sutures, it must be placed within the atrioventricular groove with great care to prevent tissue damage to the heart.

[009] Therefore, it would be desirable to provide a device, system, and method for treating mitral valve regurgitation that overcome the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

[0010] One aspect of the present invention is a device for contracting tissue in a mammalian body, comprising a body and a plurality of legs radially splayed from the body. Each leg includes a snap-acting spring tip for piercing engagement with the tissue. A sufficient axial force will transform the device from a deployed state to a treatment state under the action of the snap-acting spring tips. The treatment state will apply contraction force to the tissue engaged by the tips. Each leg may further include at least one deformation element that plastically bends in response to application of the sufficient force.

[0011] Another aspect of the present invention is a system for contracting tissue in a mammalian body that includes the above-described contracting device and further comprises a delivery catheter. The contracting device is elastically collapsible to be slidably received within a lumen of the delivery catheter.

[0012] Yet, another aspect of the present invention is a method of contracting tissue in a mammalian body. A contracting device is delivered in a lumen of a catheter proximate a treatment area. The contracting device is released from the catheter. Legs of the contracting device are positioned on tissue to be contracted. An axial force is exerted on the contracting device. The force is redirected. A compass of the tissue is reduced in response to the redirection of the force.

[0013] The aforementioned and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the

accompanying drawings, which are not to scale. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** is an isometric view of one embodiment of a device for contracting tissue in a mammalian body in accordance with the present invention, the device being shown in its deployed state;

[0015] **FIG. 2** is an isometric view of the device of **FIG. 1** shown in its treatment state;

[0016] **FIGS. 3** and **4** are illustrations of the snap-acting spring tip of the device of **FIG. 1**, showing the tip at two stages of manufacture;

[0017] **FIGS. 5** and **6** are illustrations of alternative deformation elements for a leg of the device of **FIG. 1**, in accordance with the present invention;

[0018] **FIGS. 7** and **8** are longitudinal cross-sectional views of one embodiment of a system for contracting tissue in a mammalian body in accordance with the present invention, shown at two stages of deployment of the contracting device of **FIG. 1**, the contracting device being shown in toto and a guiding catheter being shown in cross section;

[0019] **FIGS. 9–13** are views showing a progression of placement of a contracting device proximate a mitral valve, in accordance with the present invention; and

[0020] **FIG. 14** is a flow diagram of one embodiment of a method of contracting tissue in a mammalian body, in accordance with the present invention.

[0021] The same reference numbers are used throughout the drawings to refer to the same parts.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0022] One aspect of the present invention is a device for contracting tissue in a mammalian body. One embodiment of the device, in accordance with the present invention, is illustrated in **FIGS. 1** and **2** at **110**. As illustrated, contracting device **110** comprises body **111** having a longitudinal axis. In the current example, three legs **112** extend from body **111** and are radially splayed about the longitudinal axis. One skilled in the art will appreciate that legs **112** may be varied in number, length, and spacing around body **111**. For example, **FIGS. 10-13** illustrate a four-legged embodiment of contracting device **110**.

[0023] Contracting device **110** is designed to be positioned using intravascular catheterization techniques. Alternatively, surgical or minimally invasive, i.e. endoscopic techniques may be used to place contracting device **110**. Although described below in the context of treating mitral valve regurgitation by radially contracting the valve annulus, the contracting device of the invention may also be deployed at other locations in the body and may be used to reduce the compass of other openings or the transverse dimensions of other structures within the body.

[0024] In the present embodiment, contracting device **110** may be fabricated from a section of tubing having evenly spaced longitudinal slots cut from one end of the tubing to form generally annular body **111** and flexible legs **112**. The slots may be, for example, rectangular, u-shaped, v-shaped, or Ω-shaped (omega-shaped). A central lumen of the tubing forms aperture **113** in body **111**. In another embodiment, contracting device **110** may be manufactured by cutting, stamping, or otherwise forming the device from flat sheets or other material not previously shaped into a tube. In any embodiment of the invention, legs **112** may be formed separately from body **111** and subsequently attached thereto, thus assembling a whole contracting device **110**.

[0025] Contracting device **110** is manufactured using one or more biocompatible materials. At least legs **112** of contracting device **110** comprise

a biocompatible material capable of being preset into a desired shape, for example that shown in **FIG. 1**. Such materials include, but are not limited to, a nickel-titanium alloy, a nickel-cobalt alloy, another cobalt alloy, a thermoset plastic, a stainless steel alloy, a suitable biocompatible shape-memory material, a suitable biocompatible superelastic material, combinations thereof, and the like. An antithrombotic component may be included in the chemical composition of a polymer used to form the device. Optionally, a polymeric or metallic device may be coated with a polymer that releases an anticoagulant and thereby reduces the risk of thrombus formation. If desired, additional therapeutic agents or combinations of agents may be used, including antibiotics and anti-inflammatories.

[0026] In the present embodiment, each leg **112** includes a snap-acting spring tip **116** at the free end of the leg (i.e., the end not attached to body **111**). To create a snap-acting spring tip **116**, a longitudinal slot **114** is formed in the free end of leg **112**, resulting in two tip segments **115**, as best seen in **FIG. 3**. The shape of slot **114** may vary from that shown. Tip segments **115** of each individual leg are overlapped and affixed one to another by, for example, spot welding, as is seen in **FIG. 4**. Snap-acting spring tip **116** thus formed is distorted out-of-plane with respect to the adjacent portion of leg **112**. This out-of-plane distortion allows snap-acting spring tip **116** to function as a bistable snap-acting element, as described in further detail below.

[0027] Spicule **117**, best seen in **FIG. 1**, is attached to the free end of each leg **112** to aid snap-acting spring tip **116** in piercing into the tissue of the valve annulus. Spicule **117** may surround, be included in, or otherwise be affixed to the joint forming snap-acting spring tip **116**. To increase the ability of legs **112** to grip the tissue of the valve annulus, at least one barb **118** is cut into each leg, with the sharp end of the barb pointing towards body **111** as seen in **FIGS. 1, 2, 5** and **6**. Pointing in this direction, the barb does not interfere with leg **112** entering the tissue of the valve annulus but barb **118** engages with the tissue when leg **112** reverses direction, thus preventing the leg from pulling back out of the valve annulus once it has entered the tissue. One

skilled in the art will recognize that other shapes and orientations of barbs may be used to secure legs **112** within the tissue of a valve annulus.

[0028] Each leg includes one or more deformation elements **119** designed to produce localized weakened areas in the leg. As will be explained more fully below, these weakened areas act as "knee" portions, allowing the legs to plastically bend in these areas. As seen in **FIGS. 1** and **2**, the deformation elements are notches, which are formed substantially opposite one another on the edges of legs **112**. In another embodiment, deformation elements **119** may be, for example, corrugations or perforations (shown in **FIGS. 5** and **6**, respectively) or other structures known in the art that are capable of locally weakening legs **112**.

[0029] During manufacture, legs **112** extend from body **111** and are heat set or otherwise preformed such that each leg **112** tends to self-deploy radially outward from the longitudinal axis of body **111** when contracting device **110** is released from a delivery catheter. **FIG. 1** shows legs **112** in their splayed, preformed configuration. **FIGS. 5** and **6** show legs prior to being preformed.

[0030] Contracting device **110** is a bistable apparatus having a first stable deployed state as shown in **FIG. 1**, where contracting device **110** has been released from a delivery catheter to assume the configuration into which legs **112** were preformed during manufacture. The device is capable of transitioning to a second stable treatment state as shown in **FIG. 2**. Transition of legs **112** and snap-acting spring tips **116** from their deployed states to their treatment states is accomplished by applying axial force to body **111**.

[0031] When axial force is applied to body **111**, snap-acting spring tips **116**, with spicules **117**, are pressed against the surface of the valve annulus and begin to pierce into the tissue of the annulus. At a certain threshold force, snap-acting spring tips **116** will transform "over-center" from their deployed state generally perpendicular to the plane of the valve annulus into their treatment state wherein they are directed generally radially inward

toward the longitudinal axis of body **111**. In addition, in response to applying the axial force, one or more weakened areas of legs **112** (the "knees" resulting from deformation elements **119**) permanently bend, deforming the device into its contracting, treatment state, as shown in **FIG. 2**. Deformation elements **119** thus act as mechanical "fuses," that respond to the axial force by "failing," thereby creating local deformations. Contracting device **110** transitions to its stable treatment state as a combination of the transformation of snap-acting spring tips **116** and the permanent bending of deformation elements **119**. In this stable treatment state, legs **112** of contracting device **110** draw the valve annulus toward its center.

[0032] In another embodiment, the entire device may be composed of a shape memory metal alloy that will achieve the desired mechanical profile (the treatment state) when the device is released from the delivery catheter.

[0033] It is desirable that contracting device **110** be visible using fluoroscopy, echocardiography, intravascular ultrasound, angioscopy, or another means of visualization to aid in positioning. Where fluoroscopy is utilized, any or all of contracting device **110** may be coated with a radiopaque material, or a radiopaque marker may be included on any portion of the device that would be useful to visualize.

[0034] Another aspect of the present invention is a system for contracting tissue in a mammalian body that includes contracting device **110** described above. System **100** is shown in **FIGS. 7–13**, and further includes delivery catheter **120** and guidewire **130**. Only a distal portion of the system is illustrated. The terms "distal" and "proximal" are used herein with reference to the treating clinician during deployment of the device; "Distal" indicates a portion distant from, or a direction away from the clinician and "proximal" indicates a portion near to, or direction towards the clinician.

[0035] System **100** is described below in the context of radially contracting a mitral valve annulus to effect a mitral valve repair. However, it may also be used to reduce the compass of other openings and structures within the body.

[0036] Besides the two stable deployment and treatment states discussed above, contracting device **110** may be deformed into a radially compressed configuration when confined within catheter **120** for delivery, as shown in **FIG. 7**. Contracting device **110** is capable of self-expansion from the radially compressed delivery configuration to the first stable deployment configuration, as shown in **FIG. 8**. The compression of contracting device **110** into the radially compressed configuration may be achieved elastically, that is, without any permanent deformation of the device.

[0037] In the present embodiment, delivery catheter **120** comprises guiding sheath **122**, holding tube **124**, push tube **126**, and balloon catheter **128**. Holding tube **124** is slidable within a lumen of guiding sheath **122**, push tube **126** is slidable within a lumen of holding tube **124**, and balloon catheter **128** is slidable within a lumen of push tube **126**. At least a portion of balloon catheter **128** is additionally slidable within aperture **113** of contracting device **110**. Thus, delivery catheter **120** comprises four separate telescoping members, each slidable to be individually extended or retracted as needed to deliver contracting device **110**.

[0038] Guiding sheath **122** comprises a flexible, biocompatible material such as polyurethane, polyethylene, nylon, or polytetrafluoroethylene (PTFE). Guiding sheath **122** has a preformed or steerable distal tip that is capable of assuming a desired bend with respect to the longitudinal axis of the sheath to aid in delivering the system. In one embodiment, this bend allows system **100** to approach the interatrial septum at the correct orientation to deliver contracting device **110** through the septum as seen in **FIG. 9**. In the illustrated embodiment, system **100** is passed through inferior vena cava **201** into right atrium **202**, then guiding sheath **122** remains within the right atrium while the holding tube and its contents pierce through interatrial septum **203** (also referred to below as the septal wall) into left atrium **204** to be positioned adjacent to mitral valve **205**. Those skilled in the art will appreciate that alternative paths are available to gain access to the mitral valve.

[0039] Holding tube **124** comprises the same or a different biocompatible material from that used to form guiding sheath **122**. Like guiding sheath **122**,

holding tube **124** has a preformed or steerable distal tip that is capable of assuming a desired bend with respect to the longitudinal axis of the tube when the tube is extended beyond guiding sheath **122**. Where the tip is preformed, the biocompatible material comprising holding tube **124** must allow the distal tip to assume a linear configuration while contained within the guiding sheath and the tip will assume the desired, preformed bend when extended beyond the distal end of guiding sheath **122**. In the embodiment shown in **FIG. 9**, the bend allows system **100** to be directed toward mitral valve **205**.

[0040] In the present embodiment, the distal end of holding tube **124** is angle-cut to form a sharp edge able to pierce through interatrial septum **203**. Thus, where contracting device **110** is to be delivered transluminally, holding tube **124** must be flexible enough to be delivered through vasculature to the treatment area while still rigid enough to pierce the septal wall.

[0041] Push tube **126** also comprises a biocompatible material. Push tube **126** must be axially flexible for transluminal delivery while being longitudinally incompressible to exert an axial force on body **111** of contracting device **110**, as described below.

[0042] In the present embodiment, balloon catheter **128** includes a single low-pressure balloon **129**. During delivery, balloon **129** is positioned between legs **112** of contracting device **110** as shown in **FIG. 7**. The balloon may be partially inflated to a diameter greater than the diameter of aperture **113** in the body of contracting device **110**, thereby serving as a retaining device for contracting device **110** during delivery.

[0043] In **FIG. 8**, contracting device **110** is shown released from delivery catheter **120** with legs **112** self-expanded, the device having assumed its stable deployed state. In the present embodiment, push tube **126** propels contracting device **110** out of holding tube **124**, at which time legs **112** self-expand or splay away from the longitudinal axis of body **111**. Alternatively, contracting device **110** may be released by retracting holding tube **124** while maintaining contracting device **110** stationary with push tube **126**. Guiding

sheath **122** is not seen in **FIG. 8** as it remains in right atrium **202**, supporting the delivery system while holding tube **124** and its contents are advanced through septal wall **203** and into position adjacent to mitral valve **205**.

[0044] As shown in **FIGS. 8** and **10**, balloon catheter **128** and push tube **126** may be extended from holding tube **124** simultaneously to maintain balloon **129** in a position distal to body **111** and substantially within legs **112**. In the present embodiment, balloon catheter **128** is directed over guidewire **130**, which is passed through mitral valve **205** prior to extending balloon catheter **128**. Balloon **129** is expanded at approximately the same time contracting device **110** is released from holding tube **124**. As seen in **FIG. 10**, balloon **129** is positioned over and partially within mitral valve **205**. Balloon **129** thus acts as both a retaining device and a positioning device to ensure proper placement of contracting device **110** over the valve annulus.

[0045] As shown in **FIG. 11**, balloon **129** is then at least partially deflated. At the same time, push tube **126** exerts an axial force on body **111** to drive contracting device **110** into contact with the mitral valve annulus (**FIG. 12**). As push tube **126**, now acting as a compression device, continues to exert an axial force on body **111**, snap-acting spring tips **116** transform "over-center" and deformation elements **119** bend locally (**FIG. 13**) to transition contracting device **110** to its treatment state having an inherent, stable contraction force directed radially inward toward the longitudinal axis of body **111**.

[0046] Once contracting device **110** has assumed its treatment state, thereby contracting the valve annulus and effecting a mitral valve repair, balloon **129** may be deflated and withdrawn through aperture **113**, allowing delivery catheter **120** to be removed from the body.

[0047] One skilled in the art will appreciate that numerous other embodiments of the system are possible, and that such embodiments are contemplated and fall within the scope of the presently claimed invention. For example, the system described above may further include a gripping device, for example biopsy forceps, for holding the contracting device until it is properly positioned upon the valve annulus. Alternatively, biopsy forceps or

another gripping device may replace both the balloon catheter and the push tube, holding the contracting device for positioning and also applying an axial force to the device, thus acting as both a positioning device and a compression device. In another alternative, the balloon catheter may be eliminated, with a push tube deploying the contracting device and a retaining device positioning the contracting device. In yet another alternative, the balloon catheter may include two balloons, one initially positioned proximal to aperture **113** and the other positioned distal to the aperture. The distal balloon is a low pressure balloon as described above, and the proximal balloon is a high pressure balloon capable both of pushing the contracting device out of the delivery catheter and of exerting an axial force on the contracting device. Still another alternative includes a magnetic guidewire positioned within the coronary sinus prior to deployment of the device in the atrium. For example, guidewire **240**, shown in phantom in **FIG. 9** may be magnetic. In this embodiment, the legs of the contracting device are magnetic. Upon deployment of the contracting device within the atrium, the magnetic guidewire acts as a positioning device to attract the contracting device, causing the contracting device to be properly drawn into position.

[0048] Another aspect of the present invention is a method of contracting tissue in a mammalian body. **FIG. 14** shows a flow diagram of one embodiment of the method in accordance with the present invention.

[0049] A contracting device is delivered in a lumen of a catheter proximate a treatment area (**Block 310**). In the present embodiment, the contracting device and catheter are those comprising system **100**, as described above.

[0050] For delivery, system **100** is in the configuration shown in **FIG. 7**, with contracting device **110** slidably received within delivery catheter **120**. Delivery catheter **120** carrying contracting device **110** is passed through the venous system and into a patient's right atrium adjacent to the mitral valve. This may be accomplished as shown in **FIG. 9**, in which delivery catheter **120** has been inserted through the femoral vein into the common iliac vein, through inferior vena cava **201** into right atrium **202**, and then at least a

portion of the delivery catheter is passed through septal wall **203** into left atrium **204** and positioned adjacent to mitral valve **205**.

[0051] Other paths are available, including through the radial vein into the brachial vein, through the subclavian vein, through the superior vena cava into the right atrium, and then transeptally into the left atrium. Yet another possible path would be through the femoral artery into the aorta, through the aortic valve into the left ventricle, and then through the mitral valve into the left atrium. Still another possible path would be through the left or right pulmonary vein directly into the left atrium. For surgical approaches with an open chest, the delivery catheter may be replaced by an elongate element such as an endoscope, or a trocar or cannula inserted directly into the superior vena cava or the aortic arch. The elongate element can then follow the same path as the catheter-based procedure to reach the left atrium, either transeptally or through the cardiac valves. Transeptal approaches, whether percutaneous or surgical, may require placement of a closure device at the transeptal puncture on removal of the catheter or other elongate element after the procedure.

[0052] The contracting device is released from the catheter (**Block 320**). In the present embodiment, this is accomplished by extending push tube **126** to propel contracting device **110** out of holding catheter **124**, as is seen in **FIG. 8**.

[0053] Legs of the contracting device are positioned on tissue to be contracted (**Block 330**). In the present embodiment, the legs are positioned on a mitral valve annulus. As described in detail above and shown in **FIG. 10**, balloon **129** of balloon catheter **128** is positioned partially within mitral valve **205**, thereby positioning legs **112** of contracting device **110** on the valve annulus.

[0054] A force is exerted on the contracting device (**Block 340**). In the present embodiment, this is accomplished by push tube **126** exerting an axial force on body **111** of contracting device **110**. The tips of legs **112** are embedded within the tissue of the valve annulus, and contracting device **110** is transformed into a treatment state (**Block 350**) by "over-center" action of

snap-acting spring tips **116** and by permanently bending deformation elements **119** to form "knees" in legs **112**. A compass of the tissue, in the present embodiment the diameter of the valve annulus, is thus reduced in response to the contracting device **110** attaining its contracted, treatment state (**Block 360**). Those of skill in the art will recognize that the phrase "diameter of the valve annulus" is used for simplicity in teaching the invention; A mitral valve is not exactly circular, being more D-shaped. Thus, it will be understood that, in the treatment state, each leg **112** of contracting device **110** may shorten a corresponding radial dimension of tissue engaged by the device.

[0055] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes and modifications that come within the meaning and range of equivalents are intended to be embraced therein.